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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,546	12/05/2003	Charles C. Raney	007404-000541	1896
41577	7590	05/14/2008	EXAMINER	
WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137				HOEKSTRA, JEFFREY GERBEN
ART UNIT		PAPER NUMBER		
3736				
NOTIFICATION DATE		DELIVERY MODE		
05/14/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@uspatent.com  
GMercer@uspatent.com  
Karla.Dirks@Roche.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/729,546	RANEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 February 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 33-36,38-42 and 48-63 is/are pending in the application.
- 4a) Of the above claim(s) 35,36,42,48 and 57 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 33,34,38-41,49-56 and 58-63 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 December 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>02/28/2008</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment filed on 02/28/2008, amended claim(s) 33, 40, 49, 55, and 58 and canceled claim(s) 37 is/are acknowledged. The current rejections of the claim(s) 33, 34, 38-41, 49-56, and 58-63 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Information Disclosure Statement***

2. The information disclosure statement(s) (IDS) submitted on 02/28/2008 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

### ***Claim Objections***

3. Claims 33 and 40 are objected to because of the following informalities: the positive recitation of “the skin in line 10 appears to lack antecedent basis and should apparently read “a skin”. Appropriate correction is required.

4. Claim 52 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claim 52 it is unclear how the limitation of “the sealing member is hydrophobic” further limits the limitation of claim 33 comprising “the sealing member has a surface that is hydrophobic”.

### ***Claim Rejections - 35 USC § 102***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 33, 34, 38-41, 49-56, and 58-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Nishikawa et al. (US 6,315,738 B1, hereinafter Nishikawa).

7. For claims 33 and 40, Nishikawa discloses a sampling system, comprising:

- a test strip (32) configured for loading into a lancing device to analyze body fluid from an incision created by the lancing device (column 2 lines 57-63 and Abstract),

wherein the test strip has a strip shape (as best seen in Figure 3), the test strip including

- a test area (32) configured to analyze the body fluid (column 1 lines 5-14);
- a sampling passageway (33) with an inlet opening (33a) that is remotely located from the test area (as best seen in Figures 4 and 12-23), the sampling passageway being sized and configured to draw the body fluid via capillary action (column 2 lines 26-31, column 4 lines 4-10, and column 10 lines 20-25), the sampling passageway extending from the inlet opening to the test area (as best seen in Figures 4 and 12-23) for transporting the body fluid from the incision to the test area via capillary action (column 2 lines 26-31, column 4 lines 4-10, and column 10 lines 20-25);

- a bottom surface (the bottom of test strip support 38) that faces the skin (200) when the test strip is received in the lancing device (as best seen in Figures 21-23);

- a recessed surface (3a) extending between the inlet opening and the bottom surface to inhibit contact of the body fluid on the skin with the bottom surface of the test strip (as best seen in Figures 4 and 12-23), wherein the recessed surface tapers away from the inlet opening to the bottom surface (as best seen in Figure 4); and
  - a sealing member (34a, 34b, 34c, 34d) projecting outwardly from the bottom surface of the test strip proximal the inlet opening (as best seen in Figures 4 and 12-23) and positioned to seal with the skin when the test strip is pressed against the skin to retain the body fluid at the inlet opening (column 12 lines 6-39);
- wherein the test strip with the sealing member is configured to be unloaded from the lancing device as a single disposable unit (column 2 lines 57-63 and Abstract), and
  - wherein the sealing member has a surface comprised of a hydrophobic material (column 11 lines 33-36) (the inherently hydrophobic polymers, including polypropylene, polyethylene, and polystyrene, positively recited in column 8 line 66 – column 9 line 7).
8. For claims 34 and 41, Nishikawa discloses a sampling system, wherein: the test strip includes an end edge (the end edge of test strip support 38) and the inlet opening is defined in the end edge (as best seen in Figures 4 and 12-23).
9. For claim 38, Nishikawa discloses a sampling system, wherein the sealing member is capable of being deformed upon pressing against the skin.

10. For claim 39, Nishikawa discloses a sampling system, wherein the test strip has a recessed surface (3a) extending between the inlet opening and the bottom surface (as best seen in Figures 4 and 12-23).

11. For claims 49 and 58, Nishikawa discloses a sampling system, wherein: the test strip includes a top surface positioned opposite the bottom surface (as best seen in Figures 4 and 12-23) and the test area includes an opening that is open at the top surface of the test strip to permit reflectance of light for optical analysis (93) (as best seen in Figures 21-23).

12. For claims 50 and 59, Nishikawa discloses a sampling system, wherein: the test strip includes a top surface (the top of test strip support 38) positioned opposite the bottom surface (as best seen in Figures 4 and 12-23) and at least a portion of the top surface is comprised of a hydrophobic material to resist flow of the body fluid along the top surface (the inherently hydrophobic polymers, including polypropylene, polyethylene, and polystyrene, positively recited in column 8 line 66 – column 9 line 7).

13. For claims 51 and 60, Nishikawa discloses a sampling system, wherein at least a portion of the bottom surface (the bottom of test strip support 38) is comprised of a hydrophobic material (the inherently hydrophobic polymers, including polypropylene, polyethylene, and polystyrene, positively recited in column 8 line 66 – column 9 line 7).

14. For claims 52 and 61, Nishikawa discloses a sampling system, wherein the sealing member is comprised of a hydrophobic material (column 11 lines 33-36) (the inherently hydrophobic polymers, including polypropylene, polyethylene, and polystyrene, positively recited in column 8 line 66 – column 9 line 7).

15. For claims 53 and 62, Nishikawa discloses a sampling system, wherein the recessed surface extends at an obtuse angle from the bottom surface to the inlet opening (as best seen in Figure 20).

16. For claims 54 and 63, Nishikawa discloses a sampling system, wherein the obtuse angle is from about 100 degrees to about 150 degrees (as best seen in Figure 20).

17. For claim 55, Nishikawa discloses a sampling system, wherein: the test strip has an end edge (the end edge of test strip support 38) and the inlet opening communicates with the end edge at a location spaced from the bottom surface (as best seen in Figures 4 and 12-23).

18. For claim 56, Nishikawa discloses a sampling system, wherein the test strip further includes first and second side edges (the side edges of test strip support 38) extending from the end edge, the sealing member extending from the first side edge to the second side edge (column 12 lines 6-39).

### ***Response to Arguments***

19. Applicant's arguments filed 02/28/2008 have been fully considered but they are not persuasive. Applicant argues the anticipatory rejection of the claims under Nishikawa.

20. Specifically Applicant argues Nishikawa fails to disclose, teach, and/or fairly suggest

- (a) "wherein the sealing member has a surface that is hydrophobic",
- (b) "wherein the sealing member is deformable upon pressing against the skin",

- (c) "wherein the test strip has a recessed surface extending between the inlet opening and the bottom surface" and "wherein the recessed surface tapers away from the inlet opening to the bottom surface", and
- (d) wherein at least a portion of the top and bottom surface are hydrophobic to resist flow of body fluid along their surface and wherein the recessed surface is hydrophobic.

21. The Examiner disagrees, maintains the rejection as set forth/reiterated above, and notes in response the following:

22. In response to Applicant's argument that Nishikawa fails to disclose, teach, and/or fairly suggest (a) "wherein the sealing member has a surface that is hydrophobic", the Examiner notes Nishikawa discloses comprising a variety of elements of the test strip of hydrophobic polymers, including polypropylene, polyethylene, and polystyrene (positively recited in column 8 line 66 – column 9 line 7), including the first and second housings and the body fluid guide (i.e. the sealing member). Nishikawa positively recites "Exemplary materials used for the first housing 2 include... polypropylene, polyethylene, and polystyrene..." (column 8 line 66 – column 9 line 7), "The material used for the second housing may be the same as the one described for the first housing 2" (column 9 lines 60-61), and "The body fluid guide 34 may be formed from the same material as the second housing 3..." (column 11 lines 33-34).

23. In response to applicant's argument that Nishikawa fails to disclose, teach, and/or fairly suggest (b) "wherein the sealing member is deformable upon pressing against the skin", a recitation of the intended use of the claimed invention must result in

a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The Examiner notes as set forth and reiterated above, the sealing member as disclosed by Nishikawa is capable of being deformed upon pressing against the skin. Moreover, the Examiner notes that as broadly as structurally claimed Applicant does not appear to define and/or limit "a" or "the skin".

24. In response to Applicant's argument that Nishikawa fails to disclose, teach, and/or fairly suggest (c) "wherein the test strip has a recessed surface extending between the inlet opening and the bottom surface" and "wherein the recessed surface tapers away from the inlet opening to the bottom surface", the Examiner notes Nishikawa teaches and shows, as set forth and reiterated above and as broadly as structurally claimed, a recessed surface (3a) extending between the inlet opening and the bottom surface to inhibit contact of the body fluid on the skin with the bottom surface of the test strip (as best seen in Figures 4 and 12-23), wherein the recessed surface tapers away from the inlet opening to the bottom surface (as best seen in Figure 4).

25. In response to Applicant's argument that Nishikawa fails to disclose, teach, and/or fairly suggest (d) wherein at least a portion of the top and bottom surface are hydrophobic to resist flow of body fluid along their surface and wherein the recessed surface is hydrophobic, the Examiner notes Nishikawa discloses comprising a variety of elements of the test strip of hydrophobic polymers, including polypropylene, polyethylene, and polystyrene (positively recited in column 8 line 66 – column 9 line 7),

including the first and second housings and the body fluid guide (i.e. the sealing member). Nishikawa positively recites "Exemplary materials used for the first housing 2 include... polypropylene, polyethylene, and polystyrene..." (column 8 line 66 – column 9 line 7), "The material used for the second housing may be the same as the one described for the first housing 2" (column 9 lines 60-61), and "The body fluid guide 34 may be formed from the same material as the second housing 3..." (column 11 lines 33-34).

***Conclusion***

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./  
Jeff Hoekstra  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736